

## REMARKS

The claims in the application are 1-20.

Favorable reconsideration of the application as amended is respectfully requested.

Claim 20 has been canceled without prejudice to eliminate the prospective double patenting rejection raised in paragraphs 1 and 2 of the Office Action.

The claims have been amended for various formal reasons, with all amendments herein well-supported throughout the present applications and drawings.

For example, the amendment to independent Claim 1 herein finds support, e.g., at page 3, lines 32-36 of the present application. Independent Claims 21-23 introduced herein (and which have been granted by the European Patent Office in counterpart European Patent No. EP 1 677 868 B1) find support, e.g., at page 8, lines 4-30 of the present application. Claim 24 introduced herein also finds support at page 3, lines 32-36 of the specification while Claim 25 corresponds to recitation found in original Claim 9.

Accordingly, the only outstanding issue is the prior art rejection of the claims. More specifically, Claims 1-3, 6-9, 14 and 16 have been rejected under 35 U.S.C. §102 as being anticipated by WO 97/21459 to Kornerup in paragraph 4 of the Office Action, while Claims 5, 10, 11 and 20 have been rejected under 35 U.S.C. §103 as obvious over this reference in paragraph 6 of the Office Action, with Claims 4 and 17-19 rejected as obvious additionally in view of U.S. Pat. No. 6,231,548 to Bassett in paragraph 7 of the Office Action, Claims 12 and 13 rejected additionally in view of U.S. Pat. No. 6,283,945 to Bierman in

paragraph 8 of the Office Action and Claim 15 rejected additionally in view of U.S. Pat. No. 6,375,639 to Duplessie et al in paragraph 9 of the Office Action.

However, it is respectfully submitted all pending claims herein are patentable over the applied art, for the following reasons (reference will be made to preferred embodiments of the present invention illustrated in the drawings of the present application).

The present invention improves reliability and accuracy of holding in place an elongated member 1 such as a cannula needle puncturing the skin of a mammal. The needle 1 penetrating the skin can be clamped in place close to the penetration point, minimizing any lever action so the needle will be firmly and reliably secured against axial movement without need for adhesive strips, glue, or the like to secure the needle 1. Additionally, comfort to a patient is improved because the clamping and holding device is kept as thin as possible. In particular, the claimed device can reliably and accurately clamp both flexible and more rigid elongated members 1 applied through the skin, without any need to bend the elongated member 1.

These and other advantages are explicitly attained by the claimed invention recited, e.g., independent Claims 1 and 21. More specifically, as recited in the claims herein, the present invention comprises, among other features, a plaster 2 arranged to cover the skin and having at least one adhesive layer 4 for being secured to the skin and an opening 9 through adhesive layer 4 for passage of the elongated member 1. Clamping means 8 are secured to the plaster 2 to clamp around the elongated member 1 when applied through the

skin and the plaster 2 is also applied to the skin around the puncturing position.

In particular, as recited in independent Claim 1, the clamping means 8 are thin, substantially flat and provided with a lateral opening 10 for laterally introducing the elongated member 1 between clamping portions 11 and 12. Furthermore, the clamping means 8 includes parts of substantially rigid material provided with the clamping portions 11 and 12 to bias from at least two different directions, against elongated member 1.

As recited in independent Claim 21, the clamping means 8 and plaster 2 are both provided with a lateral slot-formed opening 10 and 9 respectively, for introducing the elongated member 1 between the clamping portions by moving the plaster 2 and clamping means 8 laterally with respect to the elongated member 1 applied through the skin, and the clamping portions 11, 12 bear against and act upon the elongated member in a plane substantially parallel to a surface of the skin on which the plaster 2 is arranged. In preferred embodiments (Claims 22 and 23), elongated member 1 extends through clamping means 8 between clamping portions 11,12 at a large angle with respect to the thin, flat plaster 2, e.g., about 90°.

The features of the presently claimed invention together with the accompanying advantages attained thereby, are neither taught nor suggested by the applied art, for the following reasons.

It is asserted, in paragraph 4 of the Office Action, Kornerup shows "clamping means" 31 having a lateral opening 32 and composed of *substantially rigid* material provided with clamping portions 34. However, contrary to the this

assertion, this “clamping means” 31 is made from polyethylene foam (page 20, line 7), clearly not rigid material. Accordingly, this “means” (or connecting component) 31 clearly does not function as a clamp, unlike clamping portions 11, 12 of clamping means 8 in the present invention which bias against elongated member 1 from at least two different directions. Furthermore, Kornerup has been cited in the International Search Report of the priority PCT application under category “A” as merely of interest, and described at page 2, line 27– page 3, line 7 of the present application where Kornerup is distinguished from the claimed invention.

As described, e.g., at this location in the present application, the clamping mechanism shown in Kornerup is rather complicated and unable to securely and firmly hold a needle or drainage tube 5. Furthermore, in Kornerup, the actual “clamping mechanism” involves running the flexible tube in a groove 65 running parallel to the surface of the fixing device 1 and skin, and then securing the tube 5 in place with securing strip 43 as shown, e.g., in Figs. 1-3 (page 9, lines 21-32). In other words, Kornerup fails to show or suggest bearing and acting against elongated member 1 in a plane substantially parallel to the surface of a skin on which the plaster 2 is arranged, as recited in independent Claim 21.

Accordingly, Kornerup fails to either anticipate or render obvious the invention recited in any pending claim herein. Bassett, Bierman and Duplessie et al fail to add anything to Kornerup et al which would render obvious the invention recited in any pending claim. In particular, Bassett has been cited in the International Search Report of the priority PCT application under category “A” as

merely of interest, and also distinguished from the present invention at page 2, line 27– page 3, line 7 of the present application. In particular, the “plaster” or anchor pad 22 in Bassett is not penetrated by the catheter. The remaining art of record has not been applied against the claims and will not be commented upon further at this time.

Accordingly, in view of the forgoing amendment and accompanying remarks, it is respectfully submitted all claims pending herein are in condition for allowance. Please contact the undersigned attorney should there be any questions. A petition for an automatic two-month extension of time for response under 37 C.F.R. §1.136(a) is enclosed in duplicate together with the requisite petition fee.

Early favorable action is earnestly solicited.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "G. M. Kaplan", is written over a horizontal line.

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